DEPARTMENT OF HEALTH AND HUMAN SERVICES

95146d

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 15, 2004 W/L 02-05

Marc B. Parker, Managing Partner
Parker Foods, LLC
7313 E. Evans Road
Scottsdale, AZ 85260

Dear Mr. Parker:

On August 30 and September 1, 2004 this agency inspected your facility, located at the above address, and found serious deviations from the seafood HACCP regulation (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)). The observations cited are continuing deviations from 21 CFR Section 123.6, that were previously brought to your attention during two previous inspections conducted at your firm in March 2002 and March 2003. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan when necessary, that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your tuna salad and seafood salad products are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

You may find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product that you process, and you must have and implement a written HACCP plan for each identified food safety hazard, to comply with 21 CFR 123.6(a) and (b). However your firm does not have a HACCP plan for tuna salad and seafood salad to control the food safety hazards of pathogen growth and histamine formation.

Once you have developed a HACCP plan(s) that identifies specific controls in your processing operation for tuna salad and seafood salad products (i.e., critical control points, critical limits, monitoring and recordkeeping procedures, etc.), your HACCP plan(s) must be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official in your firm, to signify that the plan has been accepted for implementation by your firm.

At the conclusion of the inspection, these and additional deviations were listed on a Form FDA 483 and discussed with you. The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your processing plant is operating in compliance with all applicable requirements and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that appropriate policies and procedures are implemented to prevent recurrence of the problems. Failure to make corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

Please send your written reply to:

Pamela B. Schweikert, Director, Compliance Branch
U.S. Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, CA 92612-2445

If you have questions regarding any issue in this letter, please contact Ms. Greco, Compliance Officer at (949) 608-2959.

Sincerely,

Alonza E. Cruse
District Director

Enclosure